



K003893

JAN 17 2001

### 3.0 Summary of Safety and Effectiveness Information

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Thomas M. Maguire

**DEVICE NAME:** Maxillary Distractor

**CLASSIFICATION:** Class II, 21 CFR 872.4760 and 872.4880

**PREDICATE DEVICE:** Synthes (USA) Ratcheting Distractor

**DEVICE DESCRIPTION:** The Synthes (USA) Maxillary Distractor is an intra-oral distraction device. It features two telescoping components, with contourable legs having screw holes, that are fixed to the bone via 2.0 mm or 2.4 mm cortex screws.

**INTENDED USE:** The Synthes Maxillary Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically it is intended for distraction of the maxilla utilizing a LeFort I osteotomy in adult and pediatric populations.

**MATERIAL:** 316L Stainless Steel



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 17 2001

Mr. Thomas M. Maguire  
Project Leader, Regulatory Affairs  
Synthes (USA)  
1690 Russell Road  
P.O. Box 1766  
Paoli, Pennsylvania 19301-1222

Re: K003393  
Trade Name: Maxillary Distractor  
Regulatory Class: II  
Product Code: JEY  
Dated: October 31, 2000  
Received: November 1, 2000

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

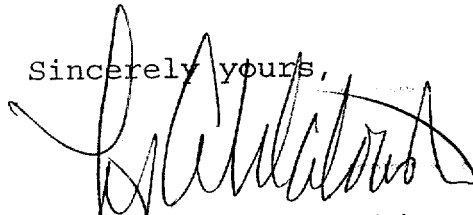
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**2.0 Indications for Use Statement**

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510(k) Number (if known): K003393

Device Name: Synthes (USA) Maxillary Distractor

Indications/Contraindications: The Synthes Maxillary Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically it is intended for distraction of the maxilla utilizing a LeFort I osteotomy in adult and pediatric populations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒   
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Susan Runyan  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K003393